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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/542,983

07/21/2005

Horst G. Zerbe

AML/13131.19

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12/23/2008

BCF LLP

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CANADA

EXAMINER

AHMED, HASAN SYED

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

12/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/542,983	Applicant(s) ZERBE ET AL.	
	Examiner HASAN S. AHMED	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 17-19, 28 and 30 is/are pending in the application.
- 4a) Of the above claim(s) 2-15, 17-19, 28 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/28/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicants' amendment/remarks, filed on 23 September 2008, and IDS, filed on 28 September 2008.

* * * * *

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 remains rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,946,685 ("Edgren").

Edgren discloses a multilayer oral dosage form comprising:

- the matrix core comprising a therapeutically effective amount of a first drug wherein the matrix core allows sustained release of the first drug of instant claim 1(a) (see col. 6, line 55 – col. 7, line 54; figure 3, 13 and 14);
- the first layer in contact with the core comprising a therapeutically effective amount of a second drug wherein the first layer allows sustained release of the first drug of instant claim 1(b) (see col. 6, line 55 – col. 7, line 54; figure 3, 12 and 14); and
- the second layer in contact with the core comprising a therapeutically effective amount of a second drug wherein the second layer allows immediate

release of the second drug of instant claim 1(c) (see col. 6, line 55 – col. 7, line 54; figure 3, 15 and 16).

* * * * *

Response to Arguments

Applicants' arguments filed on 23 September 2008 have been fully considered but they are not persuasive.

Applicants argue that, "...Edgren appears to teach a dosage form that includes two instant release layers and a sustained release layer. In contrast, Applicants' claimed dosage form includes two sustained release layers...and an immediate release layer..." See remarks page 7.

Contrary to applicants' assertion, it is examiner's position that Edgren discloses two layers that can function as sustained release layers (lamina 12 and lamina 13) and one layer that is an instant release layer (coat).

Lamina 12 and lamina 13 have similar compositions (see col., 5, line 16 - col. 6, line 54). Both contain overlapping concentrations of hydroxypropylmethylcellulose (see col. 5, lines 16-25) with a degree of polymerization of 40 to 1600, a viscosity of 2 to 225,000, and a molecular weight of 7,680 to 307,200 (see col. 6, lines 42-49). Both lamina 12 and lamina 13 can comprise a single cellulose ether, a blend of two cellulose ethers, a tertiary blend comprising three cellulose ethers, etc. (see col. 5, lines 25-28). Since a composition and its properties are inseparable, examiner respectfully submits that both lamina 12 and lamina 13 can be formulated to be sustained release layers. While it is preferred that the two lamina have different cellulose ethers and that the

lamina are different with respect to ratios, amounts, thickness, etc. (see col. 5, lines 29-32), such a difference does not preclude both laminae from being sustained release formulations. Applicants are not claiming any particular sustained release profiles or that the sustained release rates be the same between the core and the first layer. As such, examiner respectfully submits that the Edgren invention reads on the instant application as claimed.

In contrast to lamina 12 and lamina 13, the coat has a completely composition (see col. 7, lines 3-31). As such, when the coat contains a drug, the drug will be released instantly in an aqueous environment (see col. 7, lines 33-35).

Applicants point to an example and a preferred embodiment indicating that lamina 13 comprises a fast drug release formulation and lamina 12 comprises a slower drug release composition (see remarks, page 7). However, disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). See MPEP 2123. Here, the broader disclosure recites similar compositions for lamina 12 and lamina 13, as explained above.

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This application contains claims 2-15, 17-19, 28, and 30 drawn to an invention nonelected with traverse in the reply filed on 27 May 2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

☆

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1618

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615